Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Precoetaneous dilatation tracheotomy usage without fiber optic bronchoscope guidance on the patients candidate for tracheostomy and admitted to the intensive care unit on reduction of postoperative complications

Protocol summary

Summary

Study is done as prospective without blinding on 80 patients with age of at least 18 years candidate for tracheostomy and admitted to the intensive care unit (ICU) at Shahid rajaee hospital during 2106-2017. Patients with great thyroid, undesirable anatomy and Placket disorder are excluded. At first, patient is placed in hyperextension position and intended site is sterile in alcohol with chlorhexidine 2%. The site between the rings 2 and 3 of chips is marked with betadine. With a scalpel, the size of 1.5 cm horizontal incision is created and is pierce with a needle in gauge of fourteen linked to syringe 10 cc content of 2 cc distilled water. The Syringe and needle are exited and Plastic cannula is placed in trachea. Then, guide wire is entered into trachea about 10 cm via plastic cannula and is passed a plastic dilator 14 french over guide wire. Plastic dilator is exited and after entering white dilator and passing rhino dilator to the skin level into trachea and then exiting rhino dilator via metal guide wire, tracheostomy tube in suitable size is placed into trachea. metal guide wire and white dilator are exited and after bilateral symmetry lung sound and confirming tracheostomy tube site into trachea, Orotracheal tube is exited. After one hour, chest x-ray is taken. Rate of Bleeding, loss of oxygen saturation less than 90%, exiting or rupture of trachea tube, incidence of pneumothorax and Subcutaneous emphysema, incorrect embedding tracheostomy tube and related death are assessed in patients to 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061923473N3**

Registration date: **2017-07-06, 1396/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-06, 1396/04/15

Registrant information

Name

Siamak Yaghuobi

Name of organization / entity

Qazvin University of Medical Sciences & Health Services

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Qazvin University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Precoetaneous dilatation tracheotomy usage without fiber optic bronchoscope guidance on the patients candidate for tracheostomy and admitted to the intensive care unit on reduction of postoperative complications

Public title
Opening the airway of neck without the use of fiber-optic bronchoscope on reduction of postoperative complications
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age˃18; the patients who were not separated from ventilator after 2 weeks. Exclusion criteria: Patients with great thyroid; Patients with undesirable anatomy (Patients with short neck and the unknown landmark); Patients with Placket disorder and disturbance in the coagulation factors; patients with BMI˃30; patients needed to the emergent airway; Patients with fracture larynx; neck pieces instability; infection site of surgery.
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Qazvin University of Medical Sciences
Street address
Shahid Bahonar Blvd., Qazvin
City
Qazin
Postal code
Approval date
2017-05-27, 1396/03/06
Ethics committee reference number
IR. QUMS.REC.1396.140

Health conditions studied

1

Description of health condition studied
Respiratory failure or disorder
ICD-10 code
J96.9
ICD-10 code description
Respiratory failure, unspecified

Primary outcomes

1

Description
Tear of endotracheal tube cuff
Timepoint
Up to 24 hours after tracheostomy
Method of measurement
observation

2

Description
Pneumothorax
Timepoint
Up to 24 hours after tracheostomy
Method of measurement
Chest x-ray

3

Description
Subcutaneous emphysema
Timepoint
Up to 24 hours after tracheostomy
Method of measurement
Touching crepitus in the subcutaneous tissue

4

Description
Bleeding
Timepoint
Up to 24 hours after tracheostomy
Method of measurement
observation

5

Description
Extubation
Timepoint
Up to 24 hours after tracheostomy
Method of measurement
observation

6

Description
Incorrect placement of a tracheostomy tube
Timepoint
Up to 24 hours after tracheostomy
Method of measurement
observation

7

Description
Hypoxia and reduce saturation O2
Timepoint
Up to 24 hours after tracheostomy
Method of measurement
Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description
Entry tracheostomy tube without fiber optics
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee hospital
Full name of responsible person
Dr.Sareh Abdollahi
Street address
Padegan street, Qazvin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Reseach, Qazvin University of Medical Sciences
Full name of responsible person
Dr. Amir Peymani
Street address
Shahid Bahonar Blvd., Qazvin
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Reseach, Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty